TITANUS®E

Ultrasonic scaler
Ablatore a ultrasuoni
Ultraschall-Zahnsteinentferner
Détartreur à ultrasons
Detartrador ultrasónico

REF 410.00.01
REF 410.00.03



CE 0051

Operating instructions
Istruzioni per l'uso
Betriebsanleitungen
Mode d'emploi
Modo de empleo

TKD

Fig. 1



Fig. 2

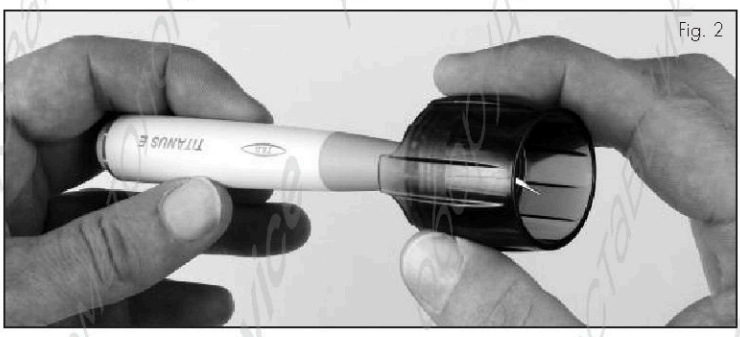


Fig. 3

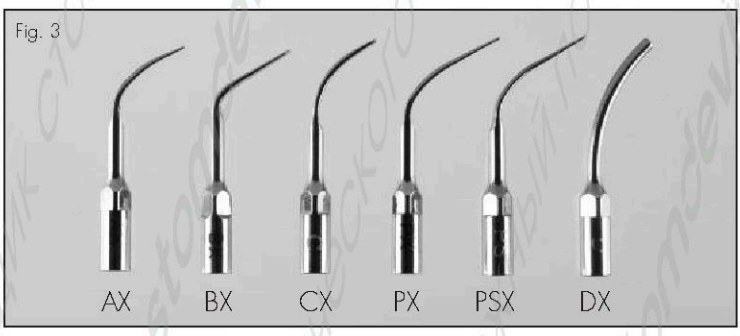


Fig. 4

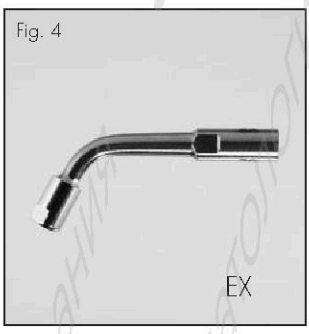
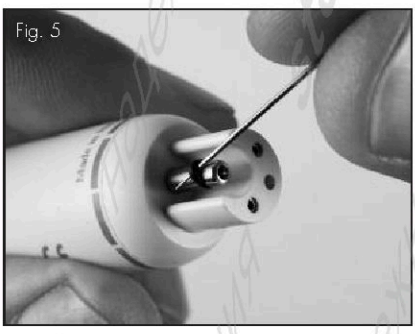


Fig. 5



ACCESSORIES AND SPARE PARTS / ACCESSORI E RICAMBI / ZUBEHÖR UND ERSATZTEILE / ACCESSOIRES ET RECHANGES / ACCESORIOS Y RECAMBIOS	
REF 001.22.03	O-rings / Guarnizioni / O-Ringe / Joints toriques / Guarniciones
REF 430.01	Insert # AX / Inserto # AX / Einsatz # AX / Insert # AX / Inserto # AX
REF 430.02	Insert # BX / Inserto # BX / Einsatz # BX / Insert # BX / Inserto # BX
REF 430.03	Insert # CX / Inserto # CX / Einsatz # CX / Insert # CX / Inserto # CX
REF 430.04	Insert # PX / Inserto # PX / Einsatz # PX / Insert # PX / Inserto # PX
REF 430.05	Insert # PSX / Inserto # PSX / Einsatz # PSX / Insert # PSX / Inserto # PSX
REF 430.07	Insert # DX / Inserto # DX / Einsatz # DX / Insert # DX / Inserto # DX
REF 430.08	Insert # EX / Inserto # EX / Einsatz # EX / Insert # EX / Inserto # EX
REF 109.00	DYNO Dynamometric wrench / Chiavetta dinamometrica / Drehmomentschlüssel / Clavette dynamométrique / Chaveta dinamométrica
REF 332.12	Light Grey silicone hose / Tubo siliconato grigio chiaro / Hellgrau Silikonschlauch / Tuyau en silicone gris clair / Manguera de silicon gris claro
REF 332.13	Grey silicone hose / Tubo siliconato grigio / Grau Silikonschlauch / Tuyau en silicone gris / Manguera de silicon gris
REF 332.17	Brown silicone hose / Tubo siliconato marrone / Braun Silikonschlauch / Tuyau en silicone brun / Manguera de silicon marrón

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ENGLISH

DESCRIPTION

Ultrasonic piezo-electric scaler for professional dental use.
The scaler can be used for prophylaxis procedures employing the TKD inserts listed below or the EMS® inserts.

This medical device meets the requirements of the European Directives 93/42/EEC (Class IIa) and 2007/47/EC.

The scaler:
- must be used only by trained and qualified personnel;
- is meant for intermittent use and the working times are shown in the technical specifications;
- does not produce electromagnetic interference;
- is not suitable for use with in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

CONTENTS

TITANUS®E scaler, insert # AX, insert # BX and insert # PX (REF 410.00.03), a DYNO dynamometric wrench, a spare O-ring for the handpiece connector.

CONNECTION OF THE HANDPIECE

After positioning the socket, the handpiece can be fitted to the original EMS® hose or TKD hose (REF 332.1x) by means of a simple snap connection (Fig.1). Do not attempt to screw.

⚠ The scaler must be connected to a power supply unit delivering maximum output voltage of 125 V_{rms}. Additionally, the power supply unit must meet the requirements of the CEI EN 60601-1 standard.

COOLING

Operating water pressure for cooling spray can be 0.6 ÷ 2.5 bar. Spray flow rate is higher than 50 ml/min. Cooling spray must be well-filtered.

⚠ As inserts heat up when used dry causing heat damage on the teeth, avoid to work dry or, in any case, use inserts without cooling for a few seconds only.

DESCRIPTION OF VIBRATIONS

All ultrasonic vibrations generated by the TITANUS®E transducer move longitudinally along the axis of the insert. Inserts therefore vibrate on a single plane and lateral vibrations, usually common to other instruments, do not exist.
For this reason, during procedure, always hold the insert tangentially to the tooth surface.

⚠ Do not direct the insert frontally to the enamel.
Never direct the tip of the insert vertically to the tooth.

FITTING OF INSERTS

Select the right shape of insert according to the treatment to be performed and screw it manually on to the handpiece (Fig.2) by means of the dynamometric wrench.
Do not fit inserts while the scaler is on.

MAINTENANCE OF THE INSERTS

The shape and weight of each insert are the result of an exact design and manufacturing so as to obtain maximum performance from the ultra-sonic transducer. Therefore any alteration due to fitting, twisting or wearing of the insert can cause anomalous operation: in such case inserts must be systematically replaced.
After every procedure, unscrew the insert by means of the dynamometric wrench and sterilise.

USE OF SUPPLIED AND OPTIONAL INSERTS (Fig.3/4)

INSERT # AX	Use: removal of supragingival tartar deposits on all tooth surfaces. For hard deposits, it is possible to set high power.	
	Power setting (min.÷max):	3 ÷ 10
INSERT # BX	Use: removal of supragingival tartar, coatings and stains on all tooth surfaces.	
	Power setting (min.÷max):	3 ÷ 10
INSERT # CX	Use: removal of heavy supragingival deposits of tartar.	
	Power setting (min. ÷ max):	3 ÷ 10
INSERT # PX	Use: removal of subgingival tartar deposits on all tooth surfaces, including interproximal and sulcus areas.	
	Power setting (min.÷max):	1 ÷ 6
INSERT # PSX	Use: removal of subgingival tartar on all root surfaces, supragingival maintenance therapy. Do not set high power.	
	Power setting (min. ÷ max):	1 ÷ 5
INSERT # DX	Use: removal of crowns, bridges and pivots.	
	Power setting (min. ÷ max):	3 ÷ 8
INSERT # EX	Special 120° ENDO chuck for use with ultrasonic files with 0.8 mm shank diameter. Do not set high power.	
	Power setting (min. ÷ max):	1 ÷ 4

The listed power values refer to settings which can be read on the potentiometer dial or LCD display of the power supply unit.
Suggested power settings are mean values given as a guide only.

REPLACEMENT OF O-RING

Should water leakage occur, replacement of the O-Ring (REF 001.22.03) on the handpiece connector is recommended.
With the aid of a pin (Fig.5), pull out the old O-ring and insert the new one on the corresponding groove.

PRELIMINARY PREPARATION

Maintenance processes are described according to ISO 17664 standard.
Before starting a process:
– Observe suitable personal protective measures against risk of infection.
– Remove all residual blood, cement or composite.
– Remove the insert from the instrument.
– Clean the medical device immediately after treatment of each patient.
Do not immerse the medical device into disinfectants solutions and do not use ultrasonic cleaning units.

CLEANING

Manual external:	Carefully clean the surfaces using a clean cloth soaked in a suitable substance. Use also a medium toothbrush and brush off under flowing hot tap water.
Manual internal:	Using a suitable spray product, follow corresponding instructions and spray the substance to the internal of the medical device. Immediately after internal cleaning, carry out the disinfection process or the drying process.
Automated:	Use a thermodisinfector complying with ISO 15883 standard which is operated with alkaline cleaning agents at a pH of maximum 10.

DISINFECTION

Manual external:	Carefully clean the surfaces using a clean cloth soave in a suitable substance (i.e. O-phenylphenol or alcohols based on ethanol). Products not recommended: disinfectants containing benzalkonium chloride, acetone or glutaraldehyde.
Manual internal:	Using a suitable spray product, follow corresponding instructions and spray the substance to the internal of the medical device. Immediately after internal disinfection, carry out the sterilization process.
Automated:	Use a thermodisinfector complying with ISO 15883 standard which is operated with alkaline disinfectant agents at a pH of maximum 10.

DRYING

Manual:	In general use dry and clean air complying to ISO 7494-2 standard.
Automated:	The drying phase is normally part of the cleaning program of the thermodisinfector.

STERILIZATION

Handpiece, wrench and inserts can be sterilised with fractioned initial vacuum phase, class B cycle according to the EN 13060 standard.
Sterilize at the nominal temperature of 134 °C (273 °F) for at least 3 min.
Use only demineralised or distilled water.
The handpiece must always be sterilised without the insert on. Use a sterilization bag.

The insert instead can be fit in and and sterilized together with the dynamometric wrench: this operation avoids any injury or contamination as it is not necessary to touch the insert.

The device is supplied "not sterile".
The device can be sterilised for at least 1000 times.

STORAGE

The processed device must be kept protected from dust and microbial contamination.

Storage temperature:	-10 ÷ 70 °C (14 ÷ 158 °F)
Storage humidity:	10 ÷ 90 %

GUARANTEE

The device carry a 24-month guarantee against all defects of construction.

SERVICE

In case of malfunction of the device and for any overhaul and repair work, please contact your usual supplier or apply directly to TKD.

REFUSE DISPOSAL

This device needs to be recycled. Electrical and electronic equipment may contain dangerous substances which constitute health and environmental hazards. The user must return the equipment to its dealer or establish direct contact with an approved body able to process and derive value from this type of equipment (European Directive 2002/96/EC).

TECHNICAL SPECIFICATIONS

Standard conformity:	ISO 22374, IEC 80601-2-60, CEI EN 60601-1, CEI EN 60601-1-2
Operating frequency:	27000 ÷ 32000 Hz.
Protection against electrical shock:	insert is a type B applied part according to CEI EN 60601-1
Max temperature of applied part:	51 °C (124 °F)
Operating Mode:	Continuos
Weight without insert:	45 g.
Working temperature:	0 ÷ 35 °C (32 ÷ 95 °F)
Working humidity:	30 ÷ 90 %

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